

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Process evaluations of complex interventions tested in randomised controlled trials in musculoskeletal disorders: a systematic review protocol
AUTHORS	Ribeiro, Daniel; Abbott, J. Haxby; Sharma, Saurab; Lamb, Sarah

VERSION 1 - REVIEW

REVIEWER	Dr Elise Gane The University of Queensland, Australia
REVIEW RETURNED	10-Dec-2018

GENERAL COMMENTS	<p>Thank you for the opportunity to review this manuscript.</p> <p>Abstract – Introduction section: For clarity, please change the research question to “How are process evaluations of complex interventions tested in randomised controlled trials in musculoskeletal disorders being conducted?” Please also make this change to the research question in the Introduction of the main body of the manuscript.</p> <p>Abstract – Methods and analysis section: For clarity, please consider rewording “non-surgical and non-pharmacological management of musculoskeletal disorders”.</p> <p>Introduction: “The burden of musculoskeletal disorders is high” – the authors might consider mentioning what kind of burden is being referred to within this sentence. The subsequent sentences refer to economic burden, however burden can also include patient pain and suffering on a personal level.</p> <p>Comment on the Introduction: The authors have done a good job of explaining the concept of process evaluations and why they are important. Well done.</p> <p>Reference to the Cochrane Qualitative and Implementation Methods Group resources is appropriate.</p> <p>Searching clinical trial registries is an important aspect of identifying suitable studies for this review – well done.</p> <p>Methods – Types of study to be included: Have the authors considered the potential to miss RCT reports that do not list secondary outcome measures such as those associated with a</p>
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	<p>process evaluation in the abstract? i.e. has the preliminary search suggested to the authors that the truly relevant studies will indeed have these outcomes listed in the abstract? (inclusion criteria relates to these being mentioned in the title or abstract).</p> <p>Methods – Intervention: Will the authors include studies that compare a surgical intervention group to a non-surgical intervention group? Please address this in the Methods.</p> <p>Methods - Risk of Bias assessment: Do the authors consider it necessary to assess the quality of the associated RCT? Would the quality of the RCT affect the quality of the process evaluation? Please discuss.</p>
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REVIEWER	Byung-Cheul Shin Pusan National University
REVIEW RETURNED	18-Dec-2018

GENERAL COMMENTS	<p>Dear authors,</p> <p>In this manuscript, the authors presented a protocol for systematic review of process evaluations of complex interventions tested in RCTs in musculoskeletal disorders. This protocol seems generally well balanced in accordance with important guidelines, therefore, I just give comments on some minor points.</p> <p>1. What are complex interventions? There is a need for explaining complex interventions more in depth. I wonder whether complex interventions differ from non-surgical and non-pharmacological interventions or same ones.</p> <p>2. I wonder whether 'Intervention' and 'Comparator(s)/control' are contexts from randomized controlled trials or not. If so, why control is 'Not applicable' from the randomized controlled trial? If not, why intervention is complex interventions itself instead of "process evaluations of complex interventions"?</p> <p>Minor points</p> <p>1. Please check your abbreviations through the manuscript. 1) In Abstract in line 23-24 of page 3, page 6, page 7, page 15, and etc randomized controlled trials -> RCTs 2) Randomized controlled trials (RCTs) in Abstract vs. Randomized clinical trials (RCTs) in page 5, Introduction</p> <p>2. Please add keywords as 'systematic review, protocol, or randomized controlled trial'</p> <p>3. The University of York Centre for Research and Dissemination (CDR) -> (CRD) in page 12</p> <p>4. Strengths and limitations of this study in page 17 Please arrange 'Strengths' first, then follow 'limitations' for better reading.</p> <p>Thank you.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s) Reports:

Reviewer: 1

Reviewer Name: Dr Elise Gane

Institution and Country: The University of Queensland, Australia Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below Thank you for the opportunity to review this manuscript.

Abstract – Introduction section: For clarity, please change the research question to “How are process evaluations of complex interventions tested in randomised controlled trials in musculoskeletal disorders being conducted?” Please also make this change to the research question in the Introduction of the main body of the manuscript.

Response: we have revised the text.

Abstract – Methods and analysis section: For clarity, please consider rewording “non-surgical and non-pharmacological management of musculoskeletal disorders”.

Response: we have revised the text.

Introduction: “The burden of musculoskeletal disorders is high” – the authors might consider mentioning what kind of burden is being referred to within this sentence. The subsequent sentences refer to economic burden, however burden can also include patient pain and suffering on a personal level.

Response: we have revised the text.

Comment on the Introduction: The authors have done a good job of explaining the concept of process evaluations and why they are important. Well done.

Response: thank you for the feedback.

Reference to the Cochrane Qualitative and Implementation Methods Group resources is appropriate.

Response: thank you for the feedback.

Searching clinical trial registries is an important aspect of identifying suitable studies for this review – well done.

Response: thank you for the feedback.

Methods – Types of study to be included: Have the authors considered the potential to miss RCT reports that do not list secondary outcome measures such as those associated with a process evaluation in the abstract? i.e. has the preliminary search suggested to the authors that the truly relevant studies will indeed have these outcomes listed in the abstract? (inclusion criteria relates to these being mentioned in the title or abstract).

Response: thank you for your comments. You are correct. It is possible that some RCTs may have not included process evaluation outcomes as secondary outcome measures. We considered and discussed this when planning the review. We decided to include only studies that explicitly mention outcome measures or aims that are linked to process evaluation. We opted for this approach to keep

it feasible to complete the review while keeping it within a broad topic (i.e. “musculoskeletal disorders”). This is a limitation of the review and we have added this in the main text.

Methods – Intervention: Will the authors include studies that compare a surgical intervention group to a non-surgical intervention group? Please address this in the Methods.

Response: we will not include any trial that has a surgical intervention group. We have revised the text to clarify this.

Methods - Risk of Bias assessment: Do the authors consider it necessary to assess the quality of the associated RCT? Would the quality of the RCT affect the quality of the process evaluation? Please discuss.

Response: thank you for your comment. Please note we will only assess risk of bias of the RCT report if process evaluation is reported within the outcome evaluation (i.e. RCT study). If process evaluation is reported as an independent study, we will assess the risk of bias of the process evaluation study alone (and not the associated RCT). We have revised the text to enhance its clarity.

Reviewer: 2

Reviewer Name: Byung-Cheul Shin

Institution and Country: Pusan National University Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below Dear authors,

In this manuscript, the authors presented a protocol for systematic review of process evaluations of complex interventions tested in RCTs in musculoskeletal disorders. This protocol seems generally well balanced in accordance with important guidelines, therefore, I just give comments on some minor points.

1. What are complex interventions? There is a need for explaining complex interventions more in depth. I wonder whether complex interventions differ from non-surgical and non-pharmacological interventions or same ones.

Response: We have revised the text to improve the definition of complex interventions.

2. I wonder whether 'Intervention' and 'Comparator(s)/control' are contexts from randomized controlled trials or not. If so, why control is 'Not applicable' from the randomized controlled trial? If not, why intervention is complex interventions itself instead of “process evaluations of complex interventions”?

Response: To address your concern, we have explicitly stated which comparators we may include and which will be used for excluding articles identified through the electronic search.

Minor points

1. Please check your abbreviations through the manuscript.

1) In Abstract in line 23-24 of page 3, page 6, page 7, page 15, and etc randomized controlled trials -> RCTs

Response: we have revised the text.

2) Randomized controlled trials (RCTs) in Abstract vs. Randomized clinical trials (RCTs) in page 5, Introduction

Response: we have revised the text.

2. Please add keywords as 'systematic review, protocol, or randomized controlled trial'

Response: revised.

3. The University of York Centre for Research and Dissemination (CDR) -> (CRD) in page 12

Response: we have revised the text.

4. Strengths and limitations of this study in page 17 Please arrange 'Strengths' first, then follow 'limitations' for better reading.

Response: we have revised the text.

Thank you.

VERSION 2 – REVIEW

REVIEWER	Elise Gane The University of Queensland, Australia
REVIEW RETURNED	05-Mar-2019

GENERAL COMMENTS	The authors have addressed all comments from reviewers to my satisfaction.
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